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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,006	09/26/2005	Balkrishen Bhat	21135P	4866

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MERCK AND CO., INC
P O BOX 2000
RAHWAY, NJ 07065-0907

EXAMINER	
CRANE, LAWRENCE E	
ART UNIT	**PAPER NUMBER**
1623	

DATE MAILED: 10/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/521,006	BHAT ET AL.	
	Examiner	Art Unit	
	L. E. Crane	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01/05/2005 (prelim. amdt)*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *03/31/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

The Abstract of the Disclosure is objected to because is does not meet the requirement of the MPEP for US application. Correction is required. See MPEP 608.01(b).

The instant "Abstract," submitted as the cover sheet for the corresponding PCT publication, is not in US format.

Claims **15-20** have been cancelled, no claims have been amended, the disclosure has been amended at page 2, and no new claims have been added as per the preliminary amendment filed December 7, 2004. One Information Disclosure Statement (1 IDS) filed March 9, 2005 has been received with all cited references and made of record.

Claims **1-14** remain in the case.

Note to applicant: when a rejection refers to a claim **X** at line y, the line number "y" is determined from the claim as previously submitted by applicant in the most recent response including ~~lines deleted by line through~~.

35 U.S.C. §101 reads as follows:

> "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title."

Claims **6 and 7** are rejected under 35 U.S.C. §101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. §101. See for example *Ex parte Dunki,* 153 USPQ 678 (Bd. App., 1967) and *Clinical Products, Ltd. v. Brenner,* 255 F. Supp. 131, 149, 149 USPQ 475 (D.D.C. 1966).

See claim **6** at line 1 wherein the term "useful" is found.

Claims **6 and 7** are rejected under 35 U.S.C. §112, fourth paragraph, as being of improper dependent form for failing to further limit the subject matter of a previous claim.

The 4th paragraph test: to be rejected the claim must affirmatively ... add "something new," which "something" is not present in the claim depended from. Claims **6 and 7** add subject matter not included within the scope of claim **5** and are therefore

properly rejected as being improperly dependent for failure to further limit the scope of the subject matter of a previous claim. See also rejection below under a different part of the statute.

Claims **1-14** are rejected under 35 U.S.C. §112, first paragraph, because the specification, while being enabled for making and using a few purine ribonucleosides and related nucleotides as potential anti-hepatitis C viral inhibitors, does not reasonably provide enablement for either the making or using of 7-deazapurine nucleoside and nucleotide analogues or the administration of mixtures of purine nucleosides/nucleotides with any other anti-HCV substance to treat either an HCV infected host or a host infected with any other virus from the family of RNA-dependent RNA viruses. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The fundamental issue here is whether practicing the full scope of the instant invention is possible without undue experimentation. As provided for in *In re Wands* (858 F.2d 731, 737; 8 USPQ 2d 1400, 1404 (Fed Cir. 1988) the minimum factors to be considered in determination of whether a conclusion of "undue experimentation" is appropriate are as follows:

A. The breadth of the claims: The breadth of the claims is deemed to be excessive because the extensive lists of substituents in claims **1-3** represents a much more extensive scope of subject matter than can reasonably be supported by the small number of examples with an equally small number of exemplified substituents present in the disclosure. .

B. The nature of the invention: the invention is directed to various 2'-methyl purine ribonucleosides and analogous 2'-methylpyrrolo[2,3-d]pyrimidine ribonucleosides and their 5'-phosphorylated derivatives, pharmaceutical compositions thereof, and the administration of these compounds to treat hepatitis C viral (HCV) infected hosts.

C. The state of the prior art: As the extensive PTO-1449 listing attests, there has been considerable activity in this art area, but the area is still under development.

D. The level of one or ordinary skill: One of ordinary skill is high when administration of less complex pyrrolo[2,3-d]pyrimidine nucleoside analogues is involved as noted in the

instant prior art of record. But the level of skill in the art is much lower to very low for multiple active ingredient administrations.

E. The level of predictability in the art: Predictability varies depending on the degree of differences in structure when comparing compounds known in the art to have anti-HCV activity, compounds alleged to be anti-HCV, and mixtures, with the highest unpredictability being assigned to the administration of mixtures of anti-HCV substances.

F. The amount of direction provided by the inventor including working examples: The instant application discloses that a small number of individual purine nucleoside analogues display test results suggesting activity against HCV in culture. However, no particular test results are reported for any specific compound, only a generic assertions of activity in two single sentences found at page 29, lines 29-30 and at page 30 at lines 22-23. And, the instant application does not disclose any test data directed to the administration of either multiple purine nucleoside or nucleotide analogues or administration of one purine nucleoside or nucleotide analogue with another anti-HCV compound as claimed in instant claims **8-10**. And the disclosure fails to provide any indication that the claimed methods of treatment extend beyond HCV infections to other members of the *RNA-dependent RNA virus* family of infections.

G. The quantity of experimentation needed to make or use the invention: Based on the content of the disclosure ion comparison with the claims, the quantity of experimentation needed to make or use the invention is deemed to be excessive because of the excessive scope of the noted compound and composition claims and because of the excessive scope of the method of treatment claims wherein multiple active ingredients are claimed to be effect in combination. In view of the reality that the "method ... comprising" language in claims **8-11** cover all combinations of the non-anticipated instantly disclosed purine nucleoside and nucleotide analogues with any other pharmaceutically active substance, it is unclear what reason applicant may provide for the extension into totally unexplored areas defined by claims **12-14**.

Claims **8 or 10** and claims **6, 7 and 12-13** are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim **6 and 7** the limitations being added to claim **5** are directed to limitations properly part of a method of treating claim, but not properly part of a pharmaceutical composition claim. Claims **6 and 7** are therefore deemed to be substantial duplicates of claim **5** and consequentially their cancellation is respectfully requested.

In claims **8 and 10** the subject matter being claimed appears to be identical. Applicant is respectfully requested to cancel one of the noted claims as superfluous, or to take other appropriate action.

In claim **12** the term "another agent active against HCV" is incomplete because the identities of all substances capable of serving as said "agent" have not been defined within the claim.

In claim **13** at lines 2-3, the terms "an inhibitor of NS3 serine protease" and "an inhibitor of inosine monophosphate dehydrogenase" are generic and therefore render the claim incomplete for failure of said claim to define what particular substances are intended to be included with the metes and bounds of the claimed subject matter.

In claim **13** at line 4, the term "alone or in combination with ribavirin or levovirin" is confusing because it is unclear what members of the previous list of substances this term applies to. A clarifying amendment is respectfully requested.

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel,* 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam,* 686 F. 2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi,* 759 F.2d 887, 225 USPQ 645 (Fed. Cir 1985); and *In re Goodman,* 29 USPQ 2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. §1.78(d).

Effective January 1, 1994, a registered attorney or agent or record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. §3.73(b).

Claims **1-14** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim(s) ***1-10*** of copending Application No. **10/517,294**. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of treating HCV and the definitions of active ingredients defined as 7-deazapurine nucleosides or nucleotides are directed to substantially overlapping subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims **6-14** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims ***1-17, 22, 24 and 29-30*** of copending Application No. **10/832,945** (See US 2004/0259934; PTO-1449 ref. **9**). Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of treating a viral infection is directed to the step of administration of the same active ingredients (7-deazapurine nucleosides including those specified in instant claim **4**) in both applications and the method step must inherently include the treatment of all viral infections because all must inherently depend on an RNA-polymerase and therefore must be sensitive to the medicinal inhibition of this enzyme.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims **1-10** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims ***1-13*** of U. S. Patent No. **6,777,395** (PTO-1449 ref. **1**). Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of treating HCV and the 7-deazapurine nucleoside active ingredients are directed to substantially overlapping subject matter.

Claims **8-14** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims ***1-6*** of copending Application No. **10/504,445**.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of treating is directed to the step of administration of the same active ingredients (7-deazapurine nucleosides including those specified in instant claim **4**) in both applications and the method step must inherently include the treatment of all viral infections because all must inherently depend on an RNA-polymerase and therefore must be sensitive to the medicinal inhibition of this enzyme.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims **1-14** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim(s) ***1-21*** of copending Application No. **11/496,338** (See WO 02/057287, PTO-1449 ref. **13**). Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of treating HCV and the definitions of active ingredients defined as 7-deazapurine nucleosides or nucleotides are directed to substantially overlapping subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

"A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent."

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States."

(e) the invention was described in

(1) an application for patent described under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application filed under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a)."

(f) he did not himself invent the subject matter sought to be patented."

Claims **1-14** are rejected under 35 U.S.C. §102(e) as being anticipated by **Haoyun et al. '256** (PTO-1449 ref. **18**).

Applicant is referred to claims ***1-24*** at pages 39-43 and the definition of substituted alkyl at pages 7-8 (N^6-(halogen-substituted) alkyl provided for), which when taken together with the subject matter encompassed by claim ***1*** anticipate the instant claimed subject matter.

Claims **1-14** are rejected under 35 U.S.C. §102(e) as being anticipated by **Girardet et al. '899** (PTO-1449 **16**).

Applicant is referred to claims ***11-12 and 17-20*** at pages 52-57and the definitions of "substituted" and "alkyl" at pages 9-10 (N^6-(halogen-substituted) alkyl provided for), which when taken together with the subject matter encompassed by claims ***1, 11 and 14*** anticipate the instant claimed subject matter.

Claims **1-14** are rejected under 35 U.S.C. §102(e) as being anticipated by **Roberts et al. '290** (PTO-1449 ref. **12**).

Applicant is referred to claims ***1-10*** wherein some of the instant claimed compounds, pharmaceutical compositions and methods of treating HCV are anticipated in light of the definition of "substituted alkyl" found in the **'290** reference at page 46. See also the specifically named compounds in claim **7** at lines 17-18, 111-112, 153-154, 197-198 and 230-231

Claims **1-14** are rejected under 35 U.S.C. §102(e) as being anticipated by **Sommadossi et al. '461** (PTO-1449 ref. **5**).

Applicant is referred to the generic claims of the underlying application which read on the instant claimed purine compounds and method of treating HCV.

Claims **1-14** are rejected under 35 U.S.C. §102(e) as being anticipated by **Sommadossi et al. '999** (PTO-1449 ref. **21**).

Applicant is referred to claims ***3 and 12-27***wherein some of the instant claimed compounds, pharmaceutical compositions and methods of treating HCV are anticipated.

Claims **1-14** are rejected under 35 U.S.C. §102(e) as being anticipated by **Carroll et al. '499** (PTO-1449 ref. **12**).

Applicant is referred to examples 135 and 139 at columns 114 and 118, respectively, and the associated experimental procedures wherein synthetic precursors with 3'- and/or 5'-protecting groups represent anticipatory subject matter. In light of the abstract of the **'499** reference, the noted compounds are also deemed to have been disclosed as effective in methods of treating HCV.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. §103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. §1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. §103(c) and potential 35 U.S.C. §§102(f) or (g) prior art under 35 U.S.C. §103(a).

Papers related to this application may be submitted to Group 1600 via facsimile transmission (FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone number to FAX (unofficially) directly to Examiner's computer is 571-273-0651. The telephone number for sending an Official FAX to the PTO is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is **571-272-0651**. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. S. Anna Jiang, can be reached at **571-272-0627**.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is **571-272-1600**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status Information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see < http://pair-direct.uspto.gov >. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

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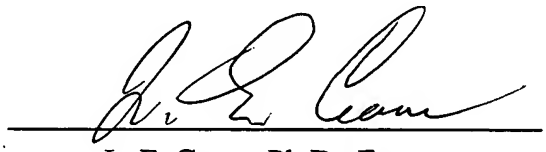

L. E. Crane, Ph.D., Esq.
Primary Patent Examiner
Technology Center 1600